Food Safety and Inspection Service

Backgrounder

December 1999

USDA Issues Final Rule on Meat and Poultry Irradiation

Summary

The Food Safety and Inspection Service (FSIS) is amending its regulations to permit the use of ionizing radiation for treating refrigerated or frozen uncooked meat, meat by-products, and certain other meat food products to reduce levels of foodborne pathogens and to extend shelf-life.

FSIS is also revising its regulations governing the irradiation of poultry products so that they will be as consistent as possible with the regulations for the irradiation of meat products.

Irradiation

Food irradiation is the process of exposing food to radiant energy in order to reduce or eliminate bacteria, therefore making it safer and more resistant to spoilage. Forms of radiant energy include: microwave and infrared radiation, which heat food during cooking; visible light or ultraviolet light, which are used to dry food or kill surface microorganisms; and ionizing radiation, which penetrates deeply into food, killing microorganisms without raising the temperature of the food significantly. Food is most often irradiated commercially to reduce the numbers of pathogenic microorganisms, to extend shelf-life, or to eliminate insect pests. Food irradiation for these purposes is practiced in many countries, including the United States.

Radiant energy is found naturally in the atmosphere, sun, soil, and water. Man-made sources of radiant energy include various x-ray machines and devices used in therapy or nuclear medicine (such as cancer therapy, thyroid therapy, and organ/cell tracing). It is also used for in vivo (in living animal) and in vitro (in a test tube or tissue culture) biological research. Consumer products treated with ionizing energy include medical bandages and dressings and other sanitary products.

People are exposed to radiation via x-rays during visits to doctors and dentists. A person will receive 40 millirems (.00000040 kiloGrays (kGy)) during a chest x-ray and 20 millirems (.00000020 kGy) during a dental x-ray. On average during the year, a person receives approximately 5 millirems (.00000005 kGy) from televisions and wristwatches. These figures are much lower than those that have been determined safe and effective for use in food.

Irradiation of meat and poultry does not increase human exposure to radiation since the energy used is not strong enough to cause food to become radioactive. During safety testing, scientists used much higher levels of radiation

than those approved for use in poultry and discovered no toxic or cancer-causing effects in animals consuming irradiated poultry. Irradiated meat and poultry products do not give off radiant energy.

Background

Food has been safely irradiated in the U.S. for over 30 years. Shortly after World War II, the U.S. Army began experimenting with irradiating fresh foods for field troops. The Food and Drug Administration (FDA), which approves food additives such as irradiation, has permitted the use of irradiation for such uses as curbing insects and microorganisms in spices and retarding spoilage in fruits and vegetables since 1963. In 1985, FDA approved irradiation for the control of Trichinella *spiralis* (which causes trichinosis) in pork.

In September 1992, FSIS approved guidelines for use of irradiation in raw packaged poultry. The FSIS decision followed FDA's May 1990 rule, which concluded that poultry irradiation at the absorbed dose of 3 kGy does not pose a safety hazard to consumers and is effective in controlling foodborne illness. FDA determined in December 1997 that use of irradiation on raw meat is safe.

Pathogenic microorganisms are the most significant cause of foodborne illness. Ionizing radiation will reduce, and in some circumstances eliminate, pathogenic microorganisms in or on meat and poultry. FSIS therefore recognizes irradiation as an important technology to help ensure the safety of meat and poultry. Ionizing irradiation is an approved additive in fresh or frozen, uncooked, packaged poultry products and mechanically separated poultry for the purpose of reducing pathogenic microorganisms.

Irradiation and HACCP

On July 25, 1996, FSIS published a final rule that requires every meat and poultry establishment to develop and implement a Hazard Analysis and Critical Control Point (HACCP) plan, a science-based process control system designed to improve the safety of meat and poultry products. Under this final rule, meat and poultry establishments are responsible for developing and implementing HACCP plans incorporating the controls determined by the establishment to be necessary and appropriate to produce safe products. HACCP is a flexible system that enables establishments to tailor their control systems to their specific needs.

FSIS is requiring that official establishments that irradiate food products do so only in accordance with a HACCP system. Because most, if not all, establishments will irradiate product specifically to reduce microbial pathogens (identified hazards), they would include irradiation as a CCP in their HACCP plans. A CCP is a point, step, or procedure at which control can be applied so that a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. Dosage, ambient temperature, oxygen levels, or other factors that affect the antimicrobial

efficacy of irradiation will likely be monitored to determine if the critical limits for an irradiation CCP are being met. By ensuring that specific limits for each of these parameters are met, establishments can be reasonably sure that a predetermined reduction in pathogens has been achieved within the irradiated product. However, irradiation does not replace sanitation systems; it is an additional tool to ensure safe, wholesome food products.

Explanation of Final Rule

The rule makes final the proposed regulations FSIS published in the February 24, 1999, *Federal Register*. More than 1,100 comments were received in response to the proposal.

The FSIS final rule specifies the same maximum absorbed dose levels for refrigerated and frozen meat as FDA's final rule (i.e., 4.5 kGy and 7.0 kGy, respectively). The maximum dosage allowed for poultry is 3 kGy, and the packaging of irradiated poultry must be air permeable.

Treating product with the maximum safe dose of irradiation allowed by the rule could result in a significant reduction or even the elimination of certain pathogens. Available scientific data indicate that ionizing radiation can significantly reduce the levels of many of the pathogenic microorganisms of concern in meat food products, including various species of *Salmonella*; *E. coli* O157:H7; *Clostridium perfringens*; *Staphylococcus aureus*; *Listeria monocytogenes*; *Campylobacter jejuni*; and the protozoan parasite *Toxoplasma gondii*.

FSIS is neither conducting special microbial testing nor requiring plants that irradiate food to do so. However, FSIS may conduct microbial testing to verify pathogen reduction claims or for enforcement purposes. Compliance with sanitation regulations, HACCP requirements and the use of irradiation will reduce the likelihood of products becoming adulterated under insanitary conditions.

FSIS also is requiring that official establishments that irradiate meat food products have in place a dosimetry system to measure absorbed doses of radiation and ensure that each lot of treated product has received the dose defined in the process schedule or HACCP plan. FSIS will allow meat and poultry establishments to determine what level of irradiation (up to a maximum level) and what consequent reduction of pathogens is appropriate within their HACCP systems. Depending on the processing environment, the type of meat or poultry product, and the type of radiation source employed, varying dosages of radiation will be appropriate.

Documentation

FSIS is requiring official establishments that irradiate meat products to have on file the following documents that relate to the establishment's compliance with other Federal requirements concerning irradiation:

- documentation that irradiation facilities that possess gamma radiation sources are licensed with the Nuclear Regulatory

Commission (NRC) or the appropriate State government acting under authority granted by the NRC, and that a worker safety program addressing Occupational Safety and Health Administration (OSHA) regulations is in place;

- documentation that irradiation facilities that use machine radiation sources are registered with the appropriate State government, if applicable;
- citations or other documents that relate to the instances in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities;
- certification by the operator that the irradiation facility's personnel are operating under the supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities;
- certification by the operator that the key irradiation personnel have been trained in food technology, irradiation processing, and radiation health and safety; and
- guarantees from the suppliers of all food-contact packaging materials that those materials comply with regulations for food irradiation processing.

Labeling Requirements

FDA has required that irradiated foods be labeled as such since 1966. In 1986, a symbol, the radura, was added to this labeling requirement.

The final rule requires labeling of irradiated meat and meat products sold at retail. FSIS is requiring that labeling for packaged meat products irradiated in their entirety must bear the international radura symbol along with a statement such as "treated with radiation" or "treated by irradiation."

The radura symbol contains simple petals (representing the food) in a broken circle (representing the rays from the energy source.)

The symbol must be placed prominently and conspicuously in conjunction with the required statement. The statement has to appear as a qualifier contiguous to the product name. For unpackaged meat products irradiated in their entirety, the agency is requiring that the radura symbol and a statement must be prominently and conspicuously displayed to purchasers either through labeling on a bulk container or some other appropriate device.

FSIS will allow labeling statements and claims regarding the beneficial effects of irradiation, provided they are truthful and not misleading. Further, FSIS is allowing optional labeling statements about the purpose for radiation processing to be included on the product label in addition to the above stated requirements. Processing documentation must

substantiate claims indicating a specific reduction in microbial pathogens. The agency will also allow labeling statements disclosing the specific source of radiation (gamma or machine source).

FSIS is also requiring that inclusion of an irradiated meat product ingredient in any multi-ingredient product be reflected in the ingredient statement on the finished product labeling.

Consumer and Worker Safety

The safety and efficacy of food irradiation, as demonstrated by many experiments and studies, is widely accepted by Federal regulatory agencies and national and international food and public health organizations. Food irradiation has been practiced in the United States for more than 30 years, and the irradiation of poultry products has been permitted and safely conducted since 1992. Industry possesses the expertise and the resources to safely and effectively irradiate meat food products.

Scientists from FDA, USDA, and the U.S. Department of Energy, as well as from many universities within the United States have reviewed several hundred studies on the effects of food irradiation and have determined that eating irradiated food does not present health risks. There is no evidence that irradiated foods present any increased risk of exposure to harmful substances over conventionally processed foods. Scientific studies have shown that irradiation does not significantly reduce nutritional quality or change food taste, texture, or appearance. Food irradiation has been approved in 37 countries for more than 40 products.

Consumers need to continue to handle and prepare irradiated meat and poultry as they would other raw products because some bacteria may survive the irradiation process, and bacteria from other foods can cross-contaminate irradiated foods.

Irradiation facilities must include many safety features to prevent both environmental and worker exposure. Strict operating procedures and proper training further enhances worker safety. The NRC, State agencies, and the U.S. Department of Transportation closely monitor the use and transportation of radioactive materials, including the equipment and the facilities in which they are used.

For More Information:

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Consumer inquiries: Call USDA's Meat and Poultry Hotline at 1-800-535-4555. In the Washington, DC, area, call (202) 720-3333. The TTY number is 1-800-256-7072.
FSIS Web site: **http://www**. *fsis.usda.gov*